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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,412	11/22/2000	Moshe Baru	107587	8564

25944 7590 08/06/2002

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EXAMINER
SCHNIZER, HOLLY G

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 08/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/673,412	BARU ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) *13-15,20 and 21* is/are allowed.

6)☐ Claim(s) *1-12,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 & 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-13 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that Claims 1-19 share the same special technical feature, linking the inventions of Groups I-V, that defines a contribution over the prior art because Woodle et al. does not teach that the therapeutic protein is not encapsulated by the liposome. This is not found persuasive because, as stated in the previous Office Action, Woodle et al. (US Patent No. 5,013,556; referenced in IDS of Paper No. 5) teaches a composition comprising a protein and a neutral colloidal particle, the particle comprising 1-20 mole percent of an amphipathic lipid (phosphatidylethanolamine) derivatized with a biocompatible hydrophilic polymer (polyethylene glycol) (see abstract). And, Woodle et al. teaches that the protein may be factor VIII (Col. 12, line 17) and that the protein may be coupled to the surface of the liposome (Col. 12, lines 4-68). Woodle et al. teach that the liposome compositions described therein provide enhancement of blood circulation lifetime (Col. 13, lines 28-30). Thus, Woodle et al. teach all of the limitations of the first claim of Group I. Applicants argument that Woodle et al. do not teach that the factor VIII is not encapsulated has been considered but not deemed persuasive. The term "encapsulated" means enclosed in a capsule. Thus, the Woodle et al. statement that the proteins can be coupled to activated liposome surface components (Col. 12, lines 67-68) is considered to mean that the proteins are coupled to the outside of the liposome and are not "encapsulated". Therefore, it appears that Groups I-V are not so

linked by the same or a corresponding special technical feature so as to form a single general inventive concept.

It is noted that upon reconsideration, the examiner has rejoined Groups I-III since examination of Groups II and III, all of which are drawn to methods and compositions involving Factor VIII, would not require an undue burden of search.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

The Preliminary Amendment filed in Paper No. 11 has been entered. Claims 20-21 have been added. Therefore, Claims 18 and 19 are withdrawn from further consideration as being drawn to non-elected subject matter and Claims 1-17 and 20-21 will be considered on the merits in this Office Action.

Drawings

The drawing filed 11-22-02 has been approved by the draftsperson.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 8, 12, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 8, and 12 are indefinite for the recitation of "between about". The term "between" is considered to be those values between those claimed whereas "about" is considered to allow for values slightly above the upper and below the lower limit of claimed ranges. Thus, the metes and bounds of the claim are unclear. The examiner suggests amending the claim to read "between 0.05 and 0.4 microns" if the values are strictly between values 0.05-0.4 microns or to read "about 0.05 to about 0.4 microns" if the range boundaries are to be more flexible.

Claims 16 and 17 provide for the use of a colloidal particle in the preparation of factor VIII, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

Claims 16 and 17 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodle et al. (US. Patent No. 5,013,556; cited in IDS of Paper No. 5).

Woodle et al. teach a composition comprising a protein and a neutral colloidal particle, the particle comprising 1-20 mole percent of an amphipathic lipid (phosphatidylethanolamine) derivatized with a biocompatible hydrophilic polymer (polyethylene glycol) (see abstract). And, Woodle et al. teaches that the protein may be plasma factor VIII (Col. 12, line 17) and that the protein may be coupled to the surface of the liposome (colloidal particle) (Col. 12, lines 4-68). The term "encapsulated" means enclosed in a capsule. Since Woodle et al. teach that the protein may be coupled to the surface of the liposome(colloidal particle), it is considered that the protein is not encapsulated by the colloidal particle. Woodle et al. teach that the colloidal particles have a mean diameter of about 0.05 to about 0.5 microns (Col. 4, lines 53) and thus meets the limitations of Claims 2-3. The limitations of Claims 4 and 5 are met by Woodle et al. teaching that the amphipathic lipid is egg-phosphatidylcholine; a lipid from a natural source (see Col. 13, lines 46-47). The limitations of Claims 6-8 are met since Woodle et al. teach that the biocompatible hydrophilic polymer is polyethylene glycol (see Col. 6, lines 34-37) of preferable molecular weight of 1,000 to 5,000 daltons. The

polyethylene glycol used in the experiments of Woodle et al. has a molecular weight of 1900 daltons (Col. 13, line 68) which is considered "approximately 2000 daltons" (present clm. 9). Woodle et al. teach that the liposome compositions described therein provide enhancement of blood circulation lifetime (Col. 13, lines 28-30); the same problem addressed by the present invention.

Thus, Claims 1-11 are anticipated by Woodle et al.

Conclusions

Claims 1-12, 16, and 17 are rejected. Claims 13-15 and 20-21 appear to be in condition for allowance. While Woodle et al. teach and suggest a pharmaceutical composition like that of Claims 1-12, Woodle et al. do not teach treating a patient suffering from hemophilia with such compositions. Since factor VIII is among many other proteins that can be used with the Woodle et al. liposome and there is no teaching or suggestion to specifically select factor VIII for use in a method of treating hemophilia over the other proteins disclosed in Woodle et al., it appears that Claims 14-15 are patentable over the prior art. Moreover, there was no teaching or suggestion of compositions wherein the particle to factor VIII ratio is between about 0.1 mg/unit and about 10 mg/unit (clm. 13) wherein the colloidal particles comprise a second amphipathic lipid (clms. 20-21). Thus, it appears that Claims 13-15 and 20-21 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-

3722. The examiner can normally be reached on Mon. & Thurs., 8am-5:30pm and Tues. & Wed. 9-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703 308-0196.

Holly Schnizer
August 1, 2002

CHRISTOPHER S. F. LOW
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